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Via www.regulations.gov

Environmental Protection Agency
1200 Pennsylvania Ave., NW.
Washington, D.C. 20460

Re: **Review of the National Ambient Air Quality Standards for Ozone—Call for Scientific and Policy-Relevant Information; June 26, 2018; 83 Fed. Reg. 29,785; Docket ID: EPA–HQ–ORD–2018–0274**

The American Petroleum Institute (API) offers the following comments on the Environmental Protection Agency's (EPA) Call for Scientific and Policy-Relevant Information: Review of the National Ambient Air Quality Standards (NAAQS) for Ozone.

API is the only national trade association representing all facets of the oil and natural gas industry, which supports 10.3 million U.S. jobs and nearly 8 percent of the U.S. economy. API's more than 620 members include large integrated companies, as well as exploration and production, refining, marketing, pipeline, and marine businesses, and service and supply firms. They provide most of the nation's energy and are backed by a growing grassroots movement of more than 40 million Americans. Regulations and the required emission control requirements to attain the NAAQS can have an impact on all aspects of API member operations.

The members of API are dedicated to continuous efforts to improve the compatibility of their operations with the environment while economically developing energy resources and supplying high quality products and services to consumers. Our members recognize their responsibility to work with the public, the government, and others to develop and to use natural resources in an environmentally sound manner while protecting the health and safety of our employees and the public.

This call for information is the initial step in the NAAQS ozone review, which the Agency has stated will be complete by October 2020.[1] Of course, API supports compliance with the Clean Air Act (CAA) and its schedule requirements and this challenging schedule is in the forefront of this 5-year NAAQS ozone review. Getting this review planned out is urgent and is arguably the first step the Agency should undertake. With this priority in mind, the API comments first address how the Back-to-Basics memorandum could be incorporated into this review.

[1] May 9, 2018 E. Scot Pruitt to Assistant Administrators Back-to-Basics Process for reviewing National Ambient Air Quality Standards, page 2. https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed August 24, 2018).

API finds that an emphasis on a robust and comprehensive Integrated Review Plan (IRP) is perhaps the best path forward to meet the Agency's challenging deadline. A focused "one draft process" with clear roles and responsibilities will be key. Please find suggestions on how the Agency can meet the timeframe in the attached comments. The challenge of this schedule cannot overemphasize. The number of issues underway, not least of which is the NAAQS $PM_{2.5}$ review process, risk delaying this central objective to meet NAAQS statutory deadlines.

In this call for information EPA requests materials regarding significant new ozone research and policy-relevant issues for consideration in this review. The API comments contain input on both the research and policy-relevant issues and discuss the importance of properly characterizing background ozone as a policy relevant issue during the NAAQS ozone review.

API appreciates the opportunity to provide these comments and looks forward to remaining an engaged and supportive stakeholder as the Agency moves forward with the NAAQS ozone review. If you have any questions about these comments, please contact me at (202) 682-8568 or steichent@api.org.

Sincerely,

/s/

Ted Steichen

Comments on the

U. S. Environmental Protection Agency's

Review of the National Ambient Air Quality Standards for Ozone

Call for Scientific and Policy-Relevant Information

Docket ID: EPA–HQ–ORD–2018–0274

June 26, 2018

83 Fed. Reg. 29,785

Submitted by the

American Petroleum Institute

August 27, 2018

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I. Introduction

A. Scope of the Call for Information on Ozone NAAQS

EPA called for the submittal of information regarding significant new ozone research and policy-relevant issues for consideration in this review of the primary (health-based) and secondary (welfare-based) ozone standards.

B. Organization of these Comments

This call for information is the initial step in the NAAQS ozone review, which the Agency has stated will be complete by October 2020.[2] Of course, API supports compliance with the Clean Air Act and its schedule requirements and this challenging schedule is in the forefront of this NAAQS ozone review. Getting this review planned out is urgent and is arguably the first step the Agency should undertake. With this priority in mind, the API comments first address how the Back-to-Basic memorandum could be incorporated into this review.

API finds that an emphasis on a robust and comprehensive Integrated Review Plan (IRP) is perhaps the best path forward to meet the Agency's challenging deadline. A focused "one draft process" with clear roles and responsibilities will be key. Please find in Section II suggestions on how the Agency could meet the timeframe established in the Back-to-Basics memorandum.

In this call for information EPA requests materials regarding significant new ozone research and policy-relevant issues for consideration in this review.[3] The API research input is organized in Sections III and IV, and associated Exhibits A and B.

Section III provides an example list of studies that could form a "pivotal list" of studies that the ISA could cover. This list contains examples of recent information, some of which API anticipates EPA's Office of Research and Development (ORD) would likely select as pivotal. Please note the studies listed are not an endorsement of these studies but are listed for illustration. Exhibit A of the comments provide more detail and suggestions for how these studies could be summarized in the ISA.

Section IV and Exhibit B deal with ozone research that API suggests the Agency consider as the "pivotal list" is developed.

API comments discuss the importance of properly characterizing background ozone as a policy-relevant issue during the NAAQS ozone review in Section V and Exhibit C. Comments on adverse impacts on the NAAQS setting process will follow in response to that separate call for information.

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[2] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 2. https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed August 24, 2018).

[3] 83 Fed. Reg. 29,785 (June 26, 2018).

II. Toward a Final Ozone Rule by October 2020

In thinking about how the challenging deadline can be met API reviewed materials created by the Administration relevant to the NAAQS review process.

A. Recent Memoranda on the NAAQS Review Process

The NAAQS ozone review began with this July 2018 call for information. This upcoming review has been the subject of memoranda from the President and the EPA Administrator.

1. Presidential Memorandum of April 12, 2018 Promoting Domestic Manufacturing and Job Creation—Policies and Procedures Relating to Implementation of Air Quality Standards[4]

A key excerpt from this memo referenced future NAAQS reviews:

> *"Sec. 7. Future NAAQS Reviews. The Administrator shall evaluate whether EPA is complying fully with the requirements of section 109(d)(2)(C) of the CAA (42 U.S.C. 7409(d)(2)(C)) relating to the scope and characterization of advice provided by its Clean Air Act Scientific Advisory Committee, including requirements that the Committee advise the Administrator regarding background concentrations and adverse public health or other effects that may result from implementation of revised air quality standards. In addition, the Administrator shall examine the current NAAQS review process and develop criteria to ensure transparency in the evaluation, assessment, and characterization of scientific evidence in such reviews. The Administrator shall also develop clear guidance for differentiating the role of science and policy considerations in establishing NAAQS."*[5]

2. Administrators Back-to-Basics Process for reviewing National Ambient Air Quality Standards[6]

In this document there is substantial detail on how the Agency should refocus and reimagine the review process. In this memorandum, the Administrator set out the following five principles for EPA to observe in future NAAQS reviews:

- Meet statutory deadlines;
- Address all CAA provisions for NAAQS reviews;
- Streamline and standardize the process for development and review of key policy-relevant information;
- Differentiate science and policy judgments in the NAAQS review process; and
- Issue timely implementation regulations and guidance.

[4] 83 Fed. Reg. 16,761 (April 12, 2018).
[5] 83 Fed. Reg. 16,764 (April 16, 2018).
[6] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018.

The memorandum discusses each of the five principles and builds on early improvements to the NAAQS review process, memoranda issued December 7, 2006,[7] and May 21, 2009.[8]

Meet Statutory Deadlines is the first principle in the memorandum. The Administrator states "[f]or the next review of the ozone NAAQS, EPA shall seek efficiencies through replacing the kick-off workshop with a more robust request for information, and shall consider combining its integrated science, risk and exposure, and policy assessment into a single review.

As EPA implements this memo API encourages the Agency to look to the first document, the Integrated Review Plan (IRP) to provide the outline for this efficient review. In Part G. of this Section, API provides more detail on how the IRP and the Clean Air Scientific Advisory Committee (CASAC) review of the IRP will allow the Agency to adhere to this first principle.

Address All CAA Provisions for NAAQS Reviews is the second principle, and these provisions are specified in Section 109(d)(2) of the Act on the roles and responsibilities of CASAC. Some of these responsibilities have not been completed in past reviews and the reasons given were that EPA did not provide within the science documents material for review on all the topics mentioned in Section 109(d)(2) and that CASAC panel did not include members to address all these areas[9]. In the recent request for nominations the need for members across all the relevant disciplines was highlighted. API anxiously awaits the list of nominated panelists and intends to comment on whether or not the needed expertise will be provided on the panel. The task remains for EPA to determine how they will address all the topics that require review and if that is best incorporated in the ISA. EPA should address this issue in the IRP as to the plan to develop the needed materials for a CASAC review in the IRP.

Of note, these NAAQS topic specific panels have been constituted by the EPA Science Advisory Board (SAB) Staff Office, as compared to the statutory CASAC membership that is determined by the Administrator. Since the previous process has not provided for panels to address all the provisions, for at least this ozone panel API recommends the Administrator takes an active role to ensure this principle is fully addressed.

Streamline and standardize the process for development and review of key policy-relevant information is the third principle. The IRP should include details on how the Agency intends to meet this requirement.

Differentiate science and policy judgments in the NAAQS review process is the fourth principle. These expectations need to be enumerated and provide to the ozone NAAQS review panel as soon as it is formed. In attending many review meetings in the past API staff sensed that the CASAC panel members did not always have a common understanding of this distinction. Written expectations to the CASAC review panel would greatly improve the chances the ozone review will adhere to this principle.

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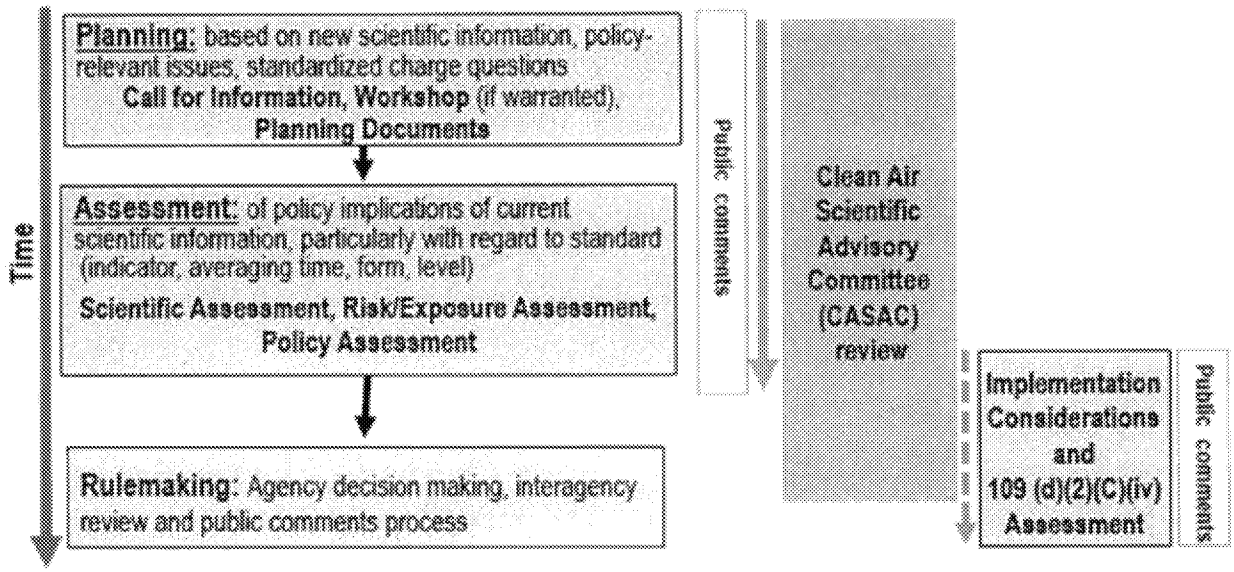
[7] Marcus Peacock: memorandum to George Gray, and Bill Wehrum, December 7, 2006. https://www3.epa.gov/ttn/naaqs/pdfs/memo_process_for_reviewing_naaqs.pdf (accessed August 24, 2018).
[8] Lisa Jackson: memorandum to Elizabeth Craig and Lek Kadeli, May 21, 2009. https://www3.epa.gov/ttn/naaqs/pdfs/NAAQSReviewProcessMemo52109.pdf (accessed August 24, 2018).
[9] Dr. H. Christopher Frey: letter to The Honorable Gina McCarthy, June 26, 2014. https://yosemite.epa.gov/sab/sabproduct.nsf/5EFA320CCAD326E885257D030071531C/$File/EPA-CASAC-14-004+unsigned.pdf (accessed August 24, 2018).

Issue timely implementation regulations and guidance is the fifth principle. This principle is important, but the challenging schedule to complete this NAAQS ozone review by October 2020 elevates the prior four principles over this one.

Within the Back-to-Basics memorandum a schematic of the steps associated with a streamlined and efficient NAAQS review is illustrated as Figure 1:[10]

Figure 1. Schematic of the steps associated with a streamlined and efficient NAAQS review.

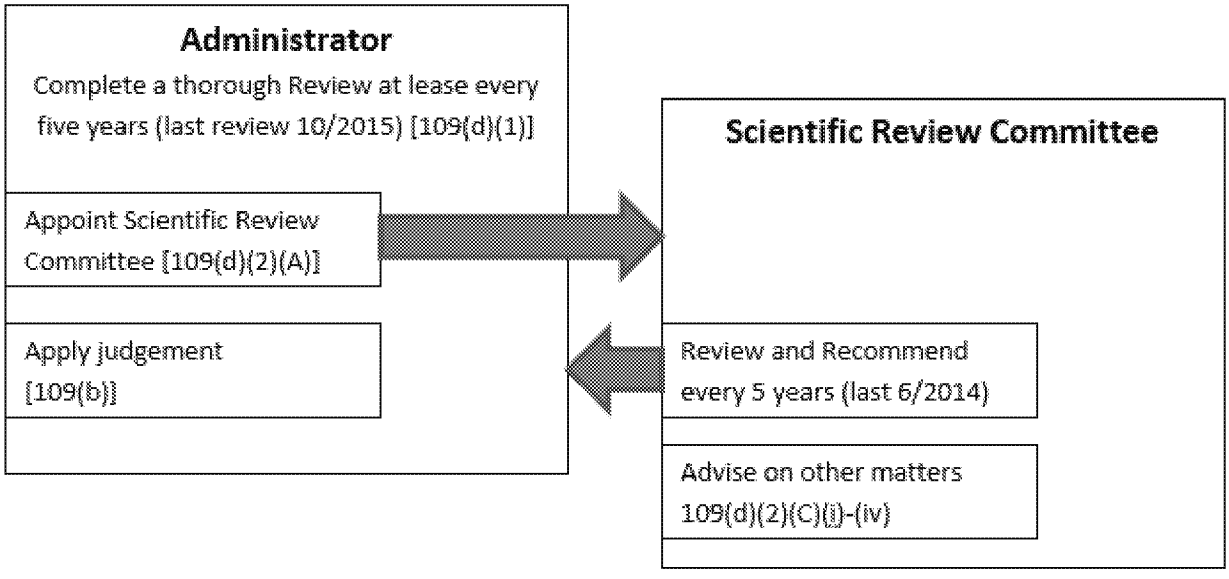


[10] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 10.

To pare this down to the minimum statutory requirements, the following illustration is provided:

Review of National Ambient Air Quality Standards

Statutory Requirements



The Administrator (EPA) prepares documents that the Scientific Review Committee, known as CASAC, review and provide recommendations. For ozone, prior to the 2015 review a Criteria Document was developed and reviewed by CASAC.[11] For the 2015 ozone review an Integrated Review Plan, Risk and Exposure Assessment Scope and Methods Plans (otherwise referred to as the Risk and Exposure Assessment Planning Documents), an Integrated Science Assessment, Risk and Exposure Assessments and a Policy Assessment were completed.

The schematic from the Back-to-Basics references all the documents that were part of the 2015 review. API recommends EPA consider whether all of these documents are necessary to produce and review. The need to do no more than necessary is critical within the timeline the Administrator has established. Please see Part B of this Section for further discussion on what API views as an aggressive timeline and provides a suggested alternative schematic in Part F of this Section.

On page 9 of the memorandum the Administrator states:

> *"EPA should strive to ensure that initial drafts of all documents are sufficiently robust and complete to serve as adequate vehicles for review from both the CASAC and the public, and CASAC should strive to focus on significant comments for these drafts to avoid multiple draft reviews whenever possible. EPA focus on providing CASAC with assessments and chapters succinctly reflect the most salient information, and CASAC focus on providing clear scientific, not editorial, advice, will prevent the inefficiency of what one former CASAC Chair called a "ping-pong" review process with review of multiple drafts. The Agency should seek additional*

[11] U.S. EPA. Air Quality Criteria for Ozone and Related Photochemical Oxidants (Second External Review Draft). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/004aB-cB, 2005. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=137307 (accessed August 24, 2018).

efficiencies in each step in the review process …, redesigning those steps as needed, and utilizing, in the most efficient manner possible, only those steps that add value in a particular review."

API strongly supports this expectation and suggests that it is best accomplished by a robust IRP that already outlines which new science may be most pivotal to review to accomplish the review. The CASAC and the public, at that point in the process, can provide feedback to the Agency to inform the development of a focused ISA. Please see Part G of this Section for further suggestions on the development of more robust IRP.

B. Aggressive Timeline

Within this call for information EPA provides a deadline to complete this review by October 2020.[12] The task before the EPA is challenging and the need to establish clear expectations and timelines for the Agency staff and CASAC is critical.

To highlight the challenge, in the last Integrated Review Plan the Call for Information (this request) was documented as being made September 2008 with a target final rule in February 2014 in the draft of the IRP,[13] and June 2014 in the final document.[14] The rule was actually finalized in October 2015[15]. The final IRP plan projected was almost 6 years, and it ended up being 7 years. The time between this Call for Information in July 2018 and the date the Administrator intends the review to be complete, October 2020, is little more than two years. Clearly to meet this new timeline will require a sweeping change in the NAAQS review process.

To add to the workload, EPA will likely need to gather additional materials that directly apply to the advice the scientific review committee (CASAC) has not traditionally provided, most especially that required in Section 109(d)(2)(C)(iv).

In considering how to implement a sweeping change, API starts with the statutory requirements and looks how to incorporate all the elements from the latest NAAQS ozone review into the minimum number of documents that require review. For example, assume the documents to be prepared are:

- Integrated Review Plan
- Integrated Science Assessment
- Materials for Section 109(d)(2)(C)(iv) (from existing materials)
- Advanced Notice of Proposed Rulemaking
- Proposed Rule
- Final Rule

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[12] E. Scot Pruitt memorandum to: EPA Assistant Administrators, May 9, 2018, page 2.
[13] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards Review - External Review Draft. U.S. Environmental Protection Agency, Washington, DC, EPA/452/D-09-001, 2009, page 14. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1005B09.txt (accessed August 24, 2018)
[14] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Washington, DC, EPA/452/R-11-006, 2011, page 2-2. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100AUZO.txt (accessed August 24, 2018)
[15] 80 Fed. Reg. 65,292 (October 26, 2015).

For illustration, please see the following possible timeline to meet the challenging schedule:

Potential NAAQS Ozone Review Milestones

Milestone	Date	Notes
Call for Information	July 2018	30-day comment period
Draft IRP	March 2019	60-day comment period
CASAC Review of IRP	April 2019	
Final IRP (becomes an element of the ISA)	July 2019	
Draft ISA & Materials for 109(d)(2)(C)(iv)	September 2019	30-day comment period
CASAC Review of ISA & Materials for 109(d)(2)(C)(iv)	October 2019	
Final ISA	December 2019	
ANPRM	February 2020	30-day comment period
Proposed Rule	May 2020	60-day comment period
Final Rule	October 2020	

The timeline allows for the development of the much more robust IRP including significant detail on the science to be reviewed and any already identified potential new risks and exposures that might need to be evaluated. Close coordination between the Office of Research and Development and the Office of Air Quality Policy and Standards within the Office of Air and Radiation would likely be the necessary to complete this draft robust IRP.

For the 2015 ozone review CASAC did not hold a meeting to discuss the draft IRP, it was discussed on a consultation conference call; CASAC provided no consensus report for the Administrator.[16] This illustrates that, in the current process, the planning phase (IRP) is not elevated to the same level as the assessment phase.

The key suggestion to EPA is to elevate the planning phase to receive the informed recommendations from the CASAC following a full review of a more robust draft IRP. The review of the ISA could then be focused on how well the IRP was followed. In Part G of this Section is a further discussion on the IRP while Part H provides discussion of the other review steps.

C. Full Requirements of the Review (CAA requirements)

Section 109(d)(2) of the Act requires appointment of an independent scientific review committee that is to periodically review the existing air quality criteria and NAAQS and to recommend any new standards and revisions of existing criteria and standards as may be appropriate. Since the early 1980s, the requirement for an independent scientific review committee has been fulfilled by the Clean Air Scientific Advisory Committee (CASAC).

Section 109(d)(2)(C) of the Act additionally requires the independent scientific review committee to advise the EPA Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised NAAQS; describe the research efforts necessary to provide the required information; advise the EPA Administrator on the relative contribution to air

[16] Dr. Jonathan M. Samet: letter to The Honorable Lisa P. Jackson, December 3, 2009 https://yosemite.epa.gov/sab/sabproduct.nsf/8A8B1D042C07DE5185257681007B7D85/$File/EPA-CASAC-10-004-unsigned.pdf (accessed August 24, 2018).

pollution concentrations of natural as well as anthropogenic activity; and, advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS. To ensure this final statutory requirement is fully met, EPA further published in the Federal Register a call for information that would facilitate the committee's consideration of these issues.

Within this call for information Federal Register Notice the CASAC requirements include:

> *"advise the EPA Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity; and, advise the EPA Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such NAAQS."*

The CASAC panel will need to include experts to address these issues and EPA will need to provide materials for CASAC review to ultimately address the noted requirements. Furthermore, API suggests that EPA prepare materials to highlight to CASAC exactly what is expected to provide this policy relevant information that can inform rule development of any new ozone NAAQS. API also suggests the Administrator identify an office within EPA to be responsible for assembling or preparing the needed documents for CASAC review on these issues.

D. Relationship with Call for Information on Adverse Impacts

The Administrator is already calling for information to evaluate the element of these CASAC review requirements dealing with adverse impacts.[17] API will comment on that call for information but strongly suggests the Agency work this issue now, before those comments are provided, to give the CASAC panel clear expectations on this task.

E. Request for Nominations for CASAC Ozone Panel

In a July 27, 2018 Notice[18] the SAB Staff Office requested public nominations for scientific experts to form a CASAC ad hoc panel to provide advice through the chartered CASAC on the scientific and technical aspects of air quality criteria and the NAAQS for ozone.

The SAB Staff Office sought nominations of nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone as they select the panel. Experts solicited include:

- Air quality,
- atmospheric science and chemistry,
- causal inference,
- dosimetry,
- toxicology,
- controlled clinical exposure,
- epidemiology,
- biostatistics,

[17] 83 Fed. Reg. 29,784 (June 26, 2018).
[18] 83 Fed Reg 35,635 (July 27, 2018).

- human exposure modeling,
- risk assessment/modeling, uncertainty analysis,
- ecology and effects on welfare and the environment, and
- environmental economics.

The approved policy[19] delegates the decision on this panel to the SAB Staff Office.

The recent request for nominations for the CASAC ozone panel[20] included the need to address the full range of the statutory CASAC duties, including an analysis of background and adverse effects. However, it did not fully highlight the needed experts to handle the full requirements of the review. In other efforts the Agency has begun to address the formation of CASAC,[21] and API recommends the Administrator continue to prioritize making further improvements in canvasing for and selecting the CASAC and the specific NAAQS review panels.

The Administrator could improve the NAAQS ozone review by guiding and supporting CASAC directly, at least as the NAAQS review process is streamlined. The repeated inability for the process to be completed within 5-years, that the full scope of the statutory advice has not been provided in recent reviews, that enhanced coordination will be necessary between ORD and OAQPS within OAR to accomplish a review redesign, and the documented substantial benefits to public health attributed to the NAAQS all argue for the Administrator's direct attention. While the SAB Staff Office has the expertise and supports numerous science panels, CASAC is pivotal to the NAAQS review process. The efficiencies of maintaining this role within the existing SAB framework could be weighed against the attention that is needed by the Administrator to ensure the advice required by the CAA is developed.

At a minimum the Administrator should update the CASAC panel formation approval policy to provide guidance to SAB Staff Office regarding CASAC. API would also suggest the Administrator ensure the CASAC panel members are provided with clear requirements and expectations of their service.

F. Overview of Possible Streamlined Process

The example schematic API provides in these comments is simplified to assist in clarifying the recommendations. These recommendations assume the same level of public interaction with the Agency and the CASAC that has historically been the case. API appreciates EPA's track record on soliciting public comment throughout the NAAQS review process. EPA's schematic provided in the recent Back-to-Basics memorandum demonstrates again its commitment to public engagement.

As with the potential scheduled provided in Part B. of this Section, API starts with the statutory requirements and examines how to incorporate all the elements from the latest NAAQS ozone review into

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[19] U.S. EPA. Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board. U.S. Environmental Protection Agency, Washington, DC, EPA–SAB–EC– 02–010, 2002. https://yosemite.epa.gov/sab/sabproduct.nsf/WebFiles/OverviewPanelForm/$File/ec02010.pdf (accessed August 24, 2018).

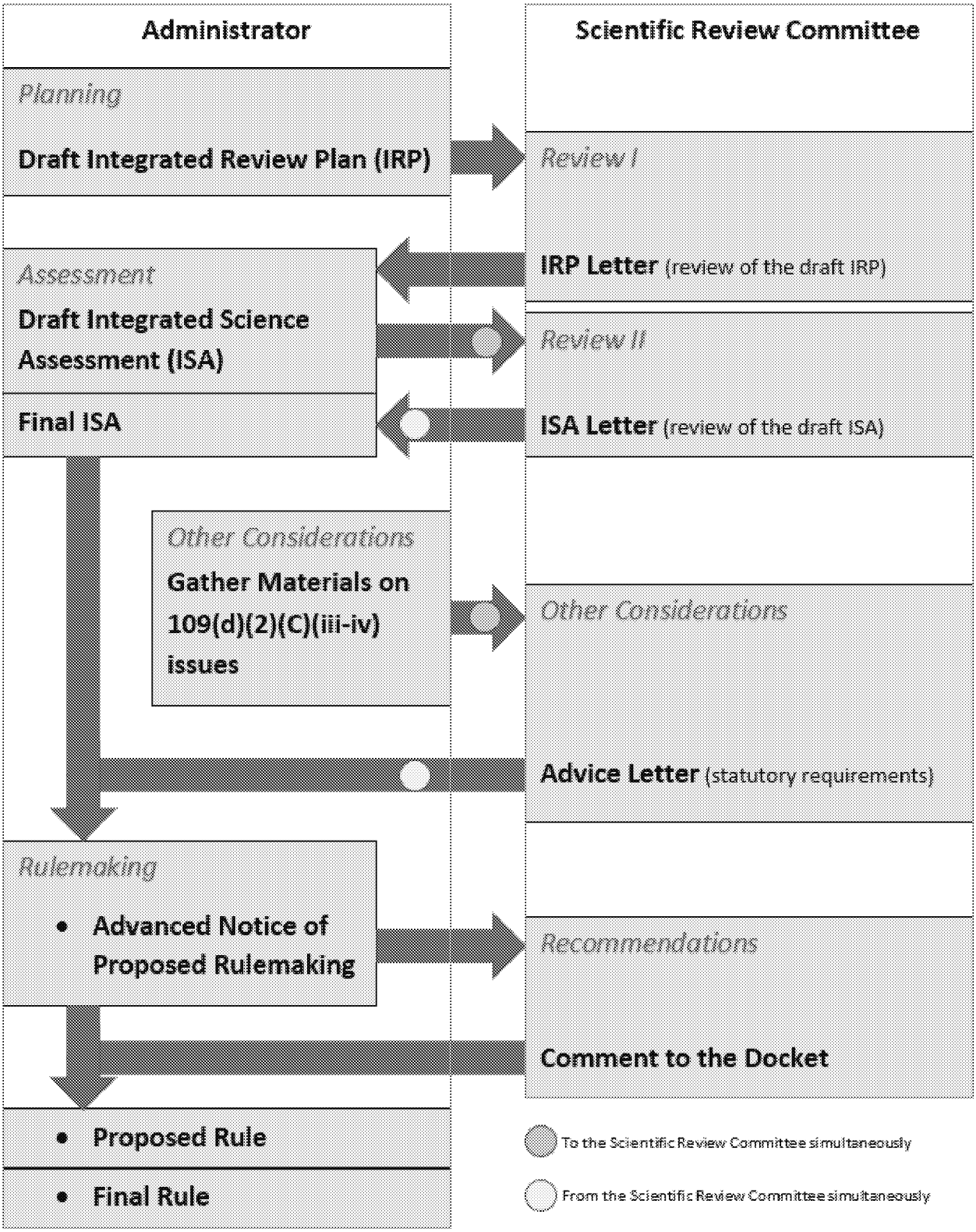
[20] 83 Fed Reg 35,635 (July 27, 2018).

[21] E. Scott Pruitt: letter to EPA Assistant Administrators, October 31, 2017. https://www.epa.gov/sites/production/files/2017-10/documents/final_draft_fac_memo-10.30.2017.pdf (accessed August 24, 2018).

the minimum number of documents that require review. For purposes of this example the documents will be prepared:

- Integrated Review Plan
- Integrated Science Assessment
- Materials for Section 109(d)(2)(C)(iv) (these are anticipated to be existing materials)
- Advanced Notice of Proposed Rulemaking
- Proposed Rule
- Final Rule

Example Review of National Ambient Air Quality Standards



The example would require two reviews by the Science Review Committee, known as CASAC. The first would be on the more robust draft IRP, the second would be for the draft ISA as well as the areas CASAC has not traditionally focused, the 109(d)(2)(C)(iv) issues discussed in Part C. of this Section.

Following those reviews the Administrator (EPA) would incorporate the recommendations from CASAC and the public and publish an Advance Notice of Proposed Rulemaking (ANPRM). Any needed materials that relate to a risk and exposure assessment that are not already incorporated in the final ISA could be included within the ANPRM or provided separately to the Docket and referenced in the ANPRM. CASAC, as a key stakeholder, would be asked to comment on the ANPRM to provide any additional advice to the Administrator prior to the proposed rule.

G. Integrated Review Plan

1. Key Review Document

As previously stated the challenging schedule requires a substantial reevaluation of the work needed on each identified step in the review process. API suggests EPA focus heavily on developing an IRP that is detailed and provides not only the process to complete the review but also identifies by name the pivotal studies the Agency will review, and how the interpretation of those studies might require further analysis of risk and exposure.

For several cycles the ozone NAAQS review process has extensively evaluated new studies to inform the level and form of the standards, though reviews have been refinements built on the existing record. In more recent years EPA staff have developed data systems that track recent research[22] so it is reasonable to assume the EPA staff experts are generally familiar with the state of the science.

To meet the challenging timeline, yet clearly meet the requirements of the CAA, API recommends EPA assemble a list of "pivotal" studies that will be investigated and discussed in the ISA. This list can and should be thoroughly reviewed by CASAC. Many of these experts, which by definition are "nationally and internationally recognized scientists with demonstrated expertise and research in the field of air pollution related to ozone",[23] can review the EPA list and identify more "pivotal" studies that should replace one on the EPA draft list. This determination of the scope of the review seems to be the highest and best use of the time committed by the CASAC ozone panel.

With the list of studies provided in the final IRP, the scope of the ISA is set and then the review can be primarily on whether the Agency had fulfilled the review as planned in the IRP.

In a similar fashion, the IRP could include the known key elements of what are now separate planning documents. Perhaps the experts at EPA can review the final REA from the last review and, in consultation with those developing the "pivotal" studies table provide at least some detail on how to address the possible need and scope of any risk or exposure assessments within the draft IRP. Again, the CASAC panelists, with their extensive knowledge are likely able to review and provide key guidance on the likely planning elements of such potential assessments by reviewing such a chapter within the draft

[22] https://hero.epa.gov/hero

[23] 83 Fed Reg 35,635 (July 27, 2018).

IRP. Inclusion of planning material about these potential assessments in the IRP will allow even more refinement of a potential plan for potential risk and exposure assessments within the draft ISA.

In both cases this robust IRP could rely on "expert elicitation" by both EPA staff and CASAC. This is a departure from prior reviews that can be made given the body of knowledge already evaluated regarding ozone and the rapid improvement in information handling capabilities. The measure of the efficacy of this approach is: does it fulfill the requirements of the statutory CASAC review. Based on the historic inability to complete the review within 5-years and the failure to address all the elements specified within the CAA, this is an example of the fresh thinking EPA should consider.

Traditionally the IRP has contained information from the prior review, summary information on new available materials and some detail on how that information will be evaluated. Each IRP has been tailored to the pollutant, but it remained very much about process and not content. In fairness, the traditional IRP content clearly does meet the definition of a review plan, but the suggestions above would make the review plan much more specific to the pollutant and the research to be reviewed in the current cycle.

More specificity earlier in the process would allow the best use of the expertise of CASAC in finalizing the IRP, as well as provide a clear framework for CASAC to ultimately judge if EPA completed what they indicated within the plan. In this approach the ISA review can be focused on evaluating the quality of the EPA effort in implementing the "plan" without needing to address the "mission creep" that API staff have observed in prior reviews where multiple ISA drafts were prepared and reviewed by CASAC. To highlight where the work has typically been focused, in the 2015 ozone review the IRP was 77 pages,[24] while the ISA was 1,251 pages.[25] In the 2008 ozone review the IRP was 22 pages,[26] while the final ISA was in three volumes with a total page count of 2,118.[27]

2. The IRP Sets the Scope of the Review

The NAAQS review process must be timely and meet the statutory requirements. An improved process should start with a detailed plan with a clear scope. Since any review is not starting from scratch and those developing the materials are already familiar with the current state of science, EPA should strongly consider focusing on developing a detailed scope of the entire NAAQS ozone review and move away from a sequential process of document development, reviews, rework of those documents and then further reviews.

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[24] U.S. EPA. Integrated Review Plan for the Ozone National Ambient Air Quality Standards. U.S. Environmental Protection Agency, Washington, DC, EPA/452/R-11-006, 2011. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100AUZO.txt (accessed August 24, 2018)

[25] U.S. EPA. Integrated Science Assessment (ISA) of Ozone and Related Photochemical Oxidants (Final Report, Feb 2013). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-10/076F, 2013. https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492 (accessed August 24, 2018).

[26] U.S. EPA. Plan for Review of the National Ambient Air Quality Standards for Ozone. U.S. Environmental Protection Agency, Washington, DC. https://www3.epa.gov/ttn/naaqs/standards/ozone/data/o3_review_plan_march05.pdf. (accessed August 24, 2018).

[27] U.S. EPA. Air Quality Criteria for Ozone and Related Photochemical Oxidants (Final Report, 2006). U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-05/004aF-cF, 2006. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=149923. (Accessed August 24, 2018).

One of the key roles of the CASAC is to describe the research efforts necessary to provide the required information. This is often done in the final letter to the Administrator on the PA.[28] Ultimately, as this NAAQS ozone review proceeds, if unexpected information comes to light it should be flagged by CASAC to investigate for the next review cycle.

3. CASAC Identified Shortcomings in Recent Integrated Review Plans

To illustrate that the current draft IRP is not necessarily sufficient within the current review process, API notes the CASAC review of EPA's Draft Integrated Review Plan for the Secondary National Ambient Air Quality Standard for Oxides of Nitrogen and Oxides of Sulfur. The then Chair of CASAC highlighted, among other items:

- Lack of Specificity in the Plan: The CASAC is concerned that providing just preliminary ideas in the draft IRP does not constitute a plan that could be put into action.[29]

- Uncertainty: A more in-depth consideration of uncertainty is needed[30]

The IRP has not always been fully reviewed by CASAC. For example, in the last review for ozone the Draft Review was a "consultation" and no consensus report was provided[31]

Using substantial EPA resources to create a more robust and specific IRP could provide the best opportunity to meet the Administrator's schedule. A more robust and specific IRP could also allow for a more substantive CASAC review of this key document. Details about how EPA will address uncertainties and highlighting the degree of transparency in the science reviewed will ultimately give the Administrator key information to evaluate any potential change in the NAAQS.

4. Charge Questions

The IRP should include charge questions that are specific to this review, perhaps directed at individual key studies and setting the expectation that the ISA identify the specific evidence within those study results that argues for a change in a NAAQS. Further charge questions can build on the identified evidence to address if the degree of uncertainty of that substantiation is more or less robust than the prior evidence used to set the existing NAAQS. All charge questions would be subject to both public and CASAC input as part of the draft IRP review defining the task in front of EPA as it develops the ISA.

5. Request for Comment by Public and CASAC

The roles and responsibilities of the Chartered CASAC and the CASAC ozone panel should be established before the first meeting. All stakeholders should be encouraged to comment on the IRP. A clear IRP can then be implemented in the ISA and the rulemaking phase.

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[28] Dr. H. Christopher Frey: letter to The Honorable Gina McCarthy, EPA-CASAC-14-004, June 26, 2014.
[29] Dr. Ana V. Diez Roux: letter to The Honorable Gina McCarthy, EPA-CASAC-16-001, April 1, 2016.
[30] Ibid, page 2
[31] Dr. John M. Samet: letter to The Honorable Lisa P. Jackson, EPA-CASAC-10-004, December 3, 2009.

6. Finalizing the IRP

EPA should incorporate, as they are able, the comments of the Public and CASAC when finalizing the IRP. An IRP specific to the pivotal science will facilitate the completion of an ISA that documents any new key evidence including a discussion of uncertainty and transparency. The finalized IRP could be incorporated in the final ISA as an appendix.

H. Other Review Steps

1. Integrated Science Assessment

Were the IRP developed as suggested, the ISA would have a clear format and would answer the specific charge questions raised by the pivotal studies indicated in the IRP to be addressed in the review. The CASAC review of the ISA would be clear. Did EPA adequately review the pivotal research identified in the IRP and complete the risk and exposure review as laid out in the IRP?

If CASAC does identify a needed improvement in the ISA, EPA could then address that in the final ISA. CASAC would also work on answering the full scope of their statutory requirements, which would be included in an advice letter to the Administrator. This letter could end the formal role of the CASAC panel, however CASAC could be encouraged to comment on the ANPRM

2. Risk and Exposure Assessment

A separate document detailing the risk and exposure assessment is not a statutory requirement. In earlier reviews the Criteria Document did not contain risk and exposure information. That information was subsequently prepared as technical documents for use by the Administrator.[32]

Incorporating risk and exposure assessments within the review process could be addressed by including these issues in both the more robust IRP and the ISA. Any available early (preliminary) results of any needed risk and exposure assessment could be included in the draft ISA. If additional risk and exposure assessments are identified, then the results could be included within the final ISA if complete at that time. If such assessments are conducted, another option would be to include the results in their entirety or by reference and place them into the Docket at the time the ANPRM is issued. CASAC could be encouraged to comment on the ANPRM.

3. Policy Assessment as an Advanced Notice of Proposed Rulemaking

The Policy Assessment (PA) could be issued as an Advanced Notice of Proposed Rulemaking (ANPRM) as outlined in the 2006 Memorandum from the Deputy Administrator Marcus Peacock.[33] The ANPRM should have a relatively short comment period and not be held up by the practice of waiting for a CASAC meeting to be held to review the PA. At the time of the ANPRM the CASAC ozone panel could review the ANPRM and update their recommendations to the Administrator via the Docket.

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[32] One of the documents: A Probabilistic Assessment of Health Risks Associated with Short-Term Exposure to Tropospheric Ozone; R,G,Whitfield, W.F. Biller, M.J. Jusko, and J.M. Keisler, ANL/DOS-3, June 1996. https://www3.epa.gov/ttn/naaqs/standards/ozone/data/riskrep.pdf (accessed August 24, 2018).

[33] Marcus Peacock: memorandum to George Gray, and Bill Wehrum, December 7, 2006. https://www3.epa.gov/ttn/naaqs/pdfs/memo_process_for_reviewing_naaqs.pdf (accessed August 24, 2018).

4. Proposed and Final Rulemaking

The release of the ANPRM could provide the opportunity to then release a proposed rule with a preferred option moving forward. After public comment, the final rule could move on to that preferred or perhaps an alternate option as laid out in the proposed rule.

III. Identify Pivotal Studies and List in the IRP

EPA should identify a limited number of truly pivotal studies that will be further evaluated in the Integrated Review Plan (IRP). The much shorter review period will require a streamlined process and EPA should fully utilize the technical expertise of EPA staff and CASAC members to establish the scope of the Integrated Science Assessment (ISA) within the IRP.

Here is an example of studies that might be included in such a focused list:

1. Long-term (chronic) effects

- **Ambient PM2.5, O_3, and NO_2 Exposures and Associations with Mortality over 16 Years of Follow-Up in the Canadian Census Health and Environment Cohort (CanCHEC);** Crouse DL, Peters PA, Hystad P, Brook JR, van Donkelaar A, Martin RV, Villeneuve PJ, Jerrett M, Goldberg MS, Pope CA 3rd, Brauer M, Brook RD, Robichaud A, Menard R, Burnett RT. *Environ Health Perspect.* 2015 Nov;123(11):1180-6.

- **Long-Term Ozone Exposure and Mortality in a Large Prospective Study;** Turner MC, Jerrett M, Pope CA 3rd, Krewski D, Gapstur SM, Diver WR, Beckerman BS, Marshall JD, Su J, Crouse DL, Burnett RT. *Am J Respir Crit Care Med.* 2016 May15;193(10):1134-42.

- **Associations between long-term PM2.5 and ozone exposure and mortality in the Canadian Census Health and Environment Cohort (CANCHEC), by spatial synoptic classification zone;** Cakmak S, Hebbern C, Pinault L, Lavigne E, Vanos J, Crouse DL, Tjepkema M. *Environ Int.* 2018 Feb;111:200-211.

- **Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States?** Cox LA Jr, Popken DA. *Ann Epidemiol.* 2015 Mar;25(3):162-73.

- **Mortality associations with long-term exposure to outdoor air pollution in a national English cohort;** Carey IM, Atkinson RW, Kent AJ, van Staa T, Cook DG, Anderson HR. *Am J Respir Crit Care Med.* 2013 Jun 1;187(11):1226-33.

- **Long-term exposure to ambient ozone and mortality: a quantitative systematic review and meta-analysis of evidence from cohort studies;** Atkinson RW, Butland BK, Dimitroulopoulou C, Heal MR, Stedman JR, Carslaw N, Jarvis D, Heaviside C, Vardoulakis S, Walton H, Anderson HR. *BMJ Open.* 2016 Feb23;6(2):e00949.

- **Ambient ozone and incident diabetes: A prospective analysis in a large cohort of African American women;** Jerrett M, Brook R, White LF, Burnett RT, Yu J, Su J, Seto E, Marshall J, Palmer JR, Rosenberg L, Coogan PF. *Environ Int.* 2017 May;102:42-47.

2. Short-term (acute) effects

- **Association of Short-term Exposure to Air Pollution with Mortality in Older Adults;** Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, Dominici F. *JAMA*. 2017 Dec 26;318(24):2446-2456

- **Characterization of the concentration-response curve for ambient ozone and acute respiratory morbidity in 5 US cities;** Barry V, Klein M, Winquist A, Chang HH, Mulholland JA, Talbott EO, Rager JR, Tolbert PE, Sarnat SE. *J Expo Sci Environ Epidemiol*. 2018 Jun 19

- **Acute effects of ambient ozone on mortality in Europe and North America: results from the APHENA study;** Peng RD, Samoli E, Pham L, Dominici F, Touloumi G, Ramsay T, Burnett RT, Krewski D, Le Tertre A, Cohen A, Atkinson RW, Anderson HR, Katsouyanni K, Samet JM. *Air Qual Atmos Health*. 2013 Jun 1;6(2):445-453

- **Air quality and acute deaths in California, 2000-2012;** Young SS, Smith RL, Lopiano KK. Air quality and acute deaths in California,2000-2012. *Regul Toxicol Pharmacol*. 2017 Aug;88:173-184

3. Respiratory Function

- **Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health;** Gilliland F, Avol E, McConnell R, Berhane K, Gauderman WJ, Lurmann FW, et al. 2017. The Effects of Policy-Driven Air Quality Improvements on Children's Respiratory Health. Research Report 190. Boston, MA:Health Effects Institute.

4. Toxicological literature

- **The perpetuation of the misconception that rats receive a 3-5 times lower lung tissue dose than humans at the same ozone concentration;** McCant D, Lange S, Haney J, Honeycutt M. *Inhal Toxicol*. 2017 Apr;29(5):187-196. doi: 10.1080/08958378.2017.1323982.

In Exhibit A to these comments is further information briefly discussing the study, conclusions and other relevant information. Also included for each of these studies is a quick strengths / limitations reference. As an example, below is the table for the first item on this list, **Ambient PM2.5, O_3, and NO_2 Exposures and Associations with Mortality over 16 Years of Follow-Up in the Canadian Census Health and Environment Cohort (CanCHEC):**

Strengths	Limitations
Large (2.5M) national 20% sample from long form Census	Lack of smoking data
Cause-specific mortality, not just all-cause	Associative, not causal modeling; standard limitations
2- and 3-p models with PM2.5 & NO2 with stable results	Hard to statistically separate pollutants' effects

IV. Additional Studies to Consider in Developing a Pivotal List

As EPA develops the list of pivotal studies to present to CASAC in the draft IRP, API offers further material in Exhibit B. In this exhibit API has included original research, methods & recommended practices, reviews, critiques, weight of evidence and commentary that can inform on the policy relevant issues associated with reviewing the ozone NAAQS.

V. Policy Relevance of Background Ozone

EPA has both the ability and legal obligation to consider the impacts of background levels of ozone on the achievability of the NAAQS. Although the U.S. Supreme Court's decision in *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457 (2001) is often cited for the proposition that EPA cannot consider the costs of implementation, EPA still can and must consider other contextual factors. Notably, in order to determine the levels of ozone that are "sufficient, but not more than necessary" to protect the public health and welfare, EPA must conduct an assessment of the extent to which the risks from exposure to the pollutant are unacceptable, which requires EPA to take into account contextual considerations. *Id.* at 473. The contextual risk assessment factors were described by Justice Breyer in *Whitman* as including "the public's ordinary tolerance of the particular health risk," "comparative health consequences," and the "acceptability of small risks to health." *Id.* At 494-95 (Breyer, J., concurring in part and concurring in the judgment). These contextual factors can all be influenced by the overall adverse economic, social, and energy impacts that could result from a revised NAAQS. For example, the public's "tolerance" and "acceptability" or a particular level of risk can be affected by the standard's adverse impacts on the public that could occur through reductions in economic growth and job loss.

Furthermore, the text of the Clean Air Act shows that Congress intended the NAAQS to be achievable by regulation of U.S. sources through State Implementation Plans (SIPs). The requirements in Section 107(a) that SIPs specify the manner in which the NAAQS "will be achieved and maintained" and the requirements in Section 110(a)(2)(C) call for an enforcement and regulation program "as necessary to assure that [NAAQS] are achieved." Furthermore, Sections 172(a)(2),181, 186, 188 and 192 specify deadlines for achieving attainment. Additionally, Section 109(b) itself links the setting of "requisite" NAAQS to their "attainment and maintenance." These attainment requirements help demonstrate that Congress did not intend NAAQS to address pollution that is beyond the control of the States or EPA. It follows that, in revising NAAQS, EPA must consider whether the standards can be achieved through the regulations provided for by the Clean Air Act – which means taking background ozone into account – and cannot set a standard that is unachievable on a nationwide basis through these regulations.

A. EPA's Identification of the Issue

As EPA states in this call for information, the EPA Administrator is to be advised on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity as part of his deliberations in setting a NAAQS.

In the ISA and the PA for the 2015 NAAQS review a summary of studies regarding background ozone and its contribution to total ambient ozone levels were provided.

B. Summarize the Key Background Studies in the IRP

EPA should start the update of background studies to include in the IRP by reviewing a key paper by Jaffe et al., 2018, *Scientific assessment of background ozone over the U.S.: Implications for air quality management*[34]. This paper considered over a 100 background ozone studies as part of an assessment of the spatial and temporal distribution, trends, and sources of background ozone over the continental U.S.

[34] Jaffe, DA, et al. 2018. Scientific assessment of background ozone over the U.S.: Implications for air quality management. Elem Sci Anth, 6:56. https://www.elementascience.org/article/10.1525/elementa.309/

Many of the referenced studies were published subsequent to the 2015 NAAQS review and should be considered as part of the current review.

The Jaffe et al. (2018) assessment found that spring and summer seasonal mean U.S. background ozone (i.e., ozone from other than U.S. anthropogenic sources) was greatest at high elevation locations in the western U.S., with monthly mean maximum daily 8-hour average (MDA8) mole fractions approaching 50 parts per billion (ppb) and annual 4th highest MDA8s exceeding 60 ppb at some locations.

C. Further Input into the Background Study Summary for the IRP

Within these comments are a list of recent studies (Exhibit C) that included information about the contribution of internationally transported ozone to U.S. background ozone. Most of these studies are included as references in the Jaffe paper; the attached list summarizes the studies' key findings.

Background ozone levels can and should be considered in setting of the NAAQS. In the previous ozone PA, EPA acknowledged that "The Administrator, when evaluating the range of possible standards that are supported by the scientific evidence, could consider proximity to background O_3 concentrations as one factor in selecting the appropriate standard."[35]

Studies listed in the previous 2015 NAAQS review, as well as those considered in the Jaffe et al. (2018) assessment show that in certain locations a significant fraction of observed ozone is due to background sources, which includes ozone derived from natural sources and international transport of ozone and its precursors. Previous studies have shown that peak background ozone exceeds 60 ppb, contributes to NAAQS exceedances, and comprises a significant fraction of seasonal mean and integrated ozone across the US. Background events are not infrequent and peak background concentrations are near the current ozone NAAQS.

EPA has historically sought to account for uncontrollable sources of ozone via implementation rules. However, in some cases the available tools and guidance to address background ozone issues may not be fully developed or functional, and states' resources to utilize the tools may be limited. While EPA should continue to improve upon implementation tools to address event-driven background ozone, it should also utilize its authority under the CAA to consider background ozone levels in setting the NAAQS.

[35] Policy Assessment for the Review of the Ozone National Ambient Air Quality Standard, Final Report , August 2014, Pg 1-27